

JUL - 5 2000

K001770



## Summary of Safety and Effectiveness

Submitter: SIMS BCI, Inc.  
Address: N7 W22025 Johnson Road  
Waukesha, WI 53186  
Telephone: (262) 542-3100  
Contact: VP Regulatory Affairs  
Prepared: May 30, 2000  
Proprietary Name: ~~BCI M4529A OEM Digital Handheld Oximeter~~  
Common/Classification Name: Pulse Oximeter  
Predicate Devices: BCI 3402 Digital Handheld Oximeter (K991410)  
HP M1191A Adult Oximetry Sensor (K882609, K990972)

### New Device Description:

The BCI M4529A OEM Digital Handheld Oximeter is an updated version of the existing BCI 3402 Digital Handheld Oximeter legally marketed by SIMS BCI. The software was modified to use the Agilent Technologies M4531A adult oximetry sensor. The Agilent Technologies M4531A sensor is the same as the HP M1191A sensor (K882609, K990972) with the exception of the connector, which has been changed to interface with the BCI oximeter.

### Intended Use:

The BCI M4529A OEM Digital Handheld Oximeter is a handheld, pulse oximeter for spot checking or continuous monitoring of SpO<sub>2</sub>, pulse rate, and pulse strength. It may be used in all critical environments, including clinical and EMS (Emergency Medical Services), patient ground transport, and for use in sleep screenings or in the home. The oximetry parameter works with the Agilent Technologies M4531A adult oximetry sensor, providing SpO<sub>2</sub> and pulse rate for adult patients. The BCI M4529A OEM Digital Handheld Oximeter permits continuous patient monitoring with adjustable alarm limits as well as visual and auditory alarm signals.

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SIMS BCI, Inc.  
N7 W22025 Johnson Road  
Waukesha, WI 53186-1856 U.S.A.  
262-542-3100 Fax: 262-542-3325

Performance Data:

The design of this device utilizes currently available technology found in many legally marketed devices. Appropriate testing was done to ensure that the BCI M4529A OEM Digital Handheld Oximeter version of the predicate BCI 3402 was safe and would perform accurately within the environment(s) for which it is to be marketed.

Safety testing was conducted in accordance with the *Reviewer's Guidance for Respiratory Devices, 1993* and EN60601-1 to ensure safe temperatures of the Agilent Technologies M4531A sensor when used with the BCI M4529A OEM Digital Handheld Oximeter.

Testing of device performance included clinical testing of the SpO<sub>2</sub> parameter and overall software validation. The results demonstrated that the BCI M4529A OEM Digital Handheld Oximeter performed within its specifications.

The testing described above indicate that there is no functional difference between the operation of the BCI M4529A OEM Digital Handheld Oximeter and the BCI 3402 Digital Handheld Oximeter. Based on these results, it is our determination that the device is safe, effective, and performs as well as the legally marketed predicate device(s).

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

Respectfully,

Donald Alexander  
VP Regulatory Affairs



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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Mr. Donald J. Alexander  
SIMS BCI, Inc.  
N7 W22025 Johnson Road  
Waukesha, WI 53186-1856

Re: K001770  
SIMS BCI M4529A OEM Digital Handheld Oximeter  
Regulatory Class: II (two)  
Product Code: 74 DQA  
Dated: June 7, 2000  
Received: June 12, 2000

Dear Mr. Alexander:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

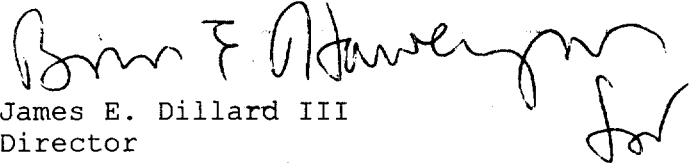
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Mr. Donald J. Alexander

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in dark ink, appearing to read "James E. Dillard III", with a stylized flourish at the end.

James E. Dillard III  
Director  
Division of Cardiovascular and  
Respiratory Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications For Use

510(k) Number (if Known): K001770

Device Name: BCI M4529A OEM Digital Handheld Oximeter


Indications For Use:

Intended Use:

The BCI M4529A OEM Digital Handheld Oximeter is a handheld, pulse oximeter for spot checking or continuous monitoring of SpO<sub>2</sub>, pulse rate, and pulse strength. It may be used in all critical environments, including clinical and EMS (Emergency Medical Services), patient ground transport, and for use in sleep studies or in the home. The oximetry parameter works with the Agilent Technologies M4531A adult oximetry sensor, providing SpO<sub>2</sub> and pulse rate for adult patients. The BCI M4529A OEM Digital Handheld Oximeter permits continuous patient monitoring with adjustable alarm limits as well as visual and auditory alarm signals.

( PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED )

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)

Division of Cardiovascular, Respiratory,  
and Neurological Devices

510(k) Number K001770

Prescription Use ☒   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ☐